

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
WASHINGTON, D.C. 20231

MAILED

Stephen Venetianer, Esquire SmithKline Beecham Corporation 709 Swedeland Road P.O. Box 1539 King of Prussia, PA 19406-0939 Re: Patent Term Extension MAR 1 8 2002

Application for

U.S. Patent No. 4,452 SEFYAM UNIT

Dear Mr. Venetianer:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 4,452,808 for a period of five years. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products). The sample format for submitting information regarding the patent and the patent expiration date to the Orange Book is available on the FDA Internet web site at: http://www.fda.gov/cder/orange/patdecl.pdf.

A certified copy of the patent term extension certificate was mailed to the address you had requested today. The original DHL Shipment Airwaybill is enclosed.

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson

Senior Legal Advisor

Office of Patent Legal Administration Office of the Deputy Commissioner for Patent Examination Policy

Enclosure:

certificate of extension

DHL label

cc:

David T. Read

Acting Director Health Assessment Policy Staff, CDER

Food and Drug Administration 1451 Rockville Pike, HFD-7 Rockville, MD 20852 RE: REQUIP

FDA Docket No.: 98E-0478

UNITED STATES PATENT AND TRADEMARK OFFICE

(12) CERTIFICATE EXTENDING PATENT TERM
UNDER 35 U.S.C. § 156

(68) PATENT NO. : 4.452.808

(45) ISSUED : June 5, 1984

(75) INVENTOR : Gregory Gallagher, Jr.

(73) PATENT OWNER: SmithKline Beecham Corporation

(95) PRODUCT : REQUIP® (ropinirole)

This is to certify that an application under 35 U.S.C. § 156 has been filed in the United States Patent and Trademark Office, requesting extension of the term of U.S. Patent No. 4,452,808 based upon the regulatory review of the product REQUIP® (ropinirole) by the Food and Drug Administration. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

(94) Five years

from December 7, 2002, the original expiration date of the patent, subject to the payment of maintenance fees as provided by law, with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).

I have caused the seal of the Patent and Trademark Office to be affixed this 12th day of March 2002.

JAMES E. ROGAN

Under Secretar of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office